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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	PAPER NUMBER
1638	

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15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,743	FISCHER ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-33* is/are pending in the application.

4a) Of the above claim(s) *9-12,14,22,23 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6-8, 13, 15-21, 24-26 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The specification and the claims have been amended as requested in the response filed 30 June 2003. Claims 1-3 and 6-33 are pending.

2. This application contains claims 9-12, 14, 22-23 and 27-29 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. The abstract is not descriptive of the instant invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed.

4. The title of the invention is not descriptive of the instant invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. The amendment filed 30 June 2003 to the paragraph beginning on line 20 of pg 43 of the specification is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: deletion of the correspondence of the consensus sequences to SEQ ID NO:2 deletes information and guidance provided by the specification as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Amendment

7. The objection to claims 5, 18 and 25 to because informalities is WITHDRAWN in light of amendment to the claims.

8. The rejection of claims 1, 4, 7-8, 13, 15-20 and 24-25 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility is WITHDRAWN in light of amendment to the claims.

9. The rejection of claims 1 and 5-6 under 35 U.S.C. 102(b) as being anticipated by Bevan et al (1 June 1998, GenBank Accession No. O49498; 23 April 1999, GenBank Accession No. T05430; and 20 April 2000, Accession No. T48453) is WITHDRAWN in light of amendment to the claims.

10. The rejection of claims 1 and 5-6 under 35 U.S.C. 102(a) as being anticipated by Lin et al (1 May 2000, Sptrembl Accession Nos. Q9SR66 and Q9SJQ6) is WITHDRAWN in light of amendment to the claims.

11. The rejection of claims 1-2, 4-7 and 15-16 under 35 U.S.C. 102(a) as being anticipated by Bevan et al (20 April 2000, Accession Nos. T48452, T48453, and 48454) is WITHDRAWN in light of amendment to the claims.

12. The rejection of claims 1-7 and 15-16 under 35 U.S.C. 102(b) as being anticipated by Rounsley et al (1997, GenBank Accession Nos. B60854 and B28303) is WITHDRAWN in light of amendment to the claims.

Claim Objections

13. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As SEQ ID NO:2 does not comprise any of SEQ ID NOs:71-73, the nucleic acid claimed in claim 3 fails to further limit the nucleic acid of claim 1.

Claim Rejections - 35 USC § 112

14. Claims 1-2, 6-8, 13, 15-21, 24-26 and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is modified from the scope of enablement rejection set forth in the Office action mailed 26 December 2002, as applied to claims 1-2, 4-8, 13, 15-21 and 24-26, due to amendment of the claims. Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids encoding proteins comprising at least one of SEQ ID NOs:71-73 and having any one of 10 biological activities, plants, cells and expression cassettes comprising those nucleic acids, and methods of using the expression cassettes to modify transcription of any gene.

The instant specification, however, only provides guidance for characterization of *Arabidopsis dmt-1 and -2* mutants, which have fertilization-independent endosperm development, created by T-DNA mutagenesis and use of the T-DNA to isolate the genomic

clone, SEQ ID NO:1, which encodes SEQ ID NO:2 (example 1); isolation of *dmt-3*, made by another T-DNA insertion, and the conclusion that all mutant alleles are loss-of-function alleles (example 2); RNA analysis in *dmt/dmt* mutants to show that they have no *MEDEA* RNA expression (example 3), generation of transgenic plants in which DMT is overexpressed from the CaMV 35S promoter to create plants in which *MEDEA* RNA levels are increased (example 3); a BLAST search of SEQ ID NO:2 to show that DMT may be a member of the HhH-GPD superfamily of DNA repair enzymes and has three domains that correspond to conserved regions of in other HhH-GPD family members (example 4); a BLAST search of databases to identify numerous related proteins and identification of consensus sequences for DMT, SEQ ID NOs:71-73 (example 4); speculation that DMT is a 5-methylcytosine glycosylase and that mutants have hypomethylation of the genome (example 5); and expression analysis of the DMT promoter, using a DMT promoter-GUS fusion gene (example 6).

The instant specification fails to provide guidance for any nucleic acids encoding proteins comprising at least one of SEQ ID NOs:71-73 and having any one of 10 biological activities, plants, cells and expression cassettes comprising those nucleic acids, and methods of using the expression cassettes to modify transcription of any gene. The protein encoded by SEQ ID NO:1 does not comprise SEQ ID NO:71, 72 or 73.

The instant specification fails to provide guidance for exact hybridization or amplification conditions and probes/primers to use in isolation of the claimed nucleic acids.

The specification, on pg 18-19, suggests making conservative substitutions to produce variant proteins. However, making "conservative" substitutions does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative"

substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1).

The specification states that SEQ ID NO:2 is related to endonuclease III, based on homology to a protein from *Deinococcus radiodurans* (pg 14, lines 18-20, and pg 40, lines 22-29, and pg 42, lines 4-24). However, this homology spans only 191 of the 1729 amino acids of SEQ ID NO:2 and is only 31.4% similar. The *D. radiodurans* protein was identified in a genomic sequencing project as an endonuclease III by its having 53.3% identity to a protein from *Methanobacterium thermautotrophium* that was identified in a genomic sequencing project as an endonuclease III by its having 35% identity to a putative endonuclease III identified in a *Methanococcus jannaschii* genomic sequencing project (see GenBank Accession Nos. AE002073, AE000855 and Q58030). This was not followed back further, but the point is clear. Identification of the protein of SEQ ID NO:2 as an endonuclease III or a related protein solely by homology to a series of putative endonuclease III proteins, and without other supporting data, like enzymatic activity studies, is speculative at best. Duggleby (1997, Gene 190:245-249) teach that "the function of any DNA sequence, whose identity is based solely on homology, can only be proven by experiments designed to evaluate that function" (pg 248, left column, paragraph 4). Additionally, an endonuclease III gene from *Arabidopsis* has been cloned (Roldán-Arjona et al,

2000, Plant Mol. Biol. 44:43-52). That protein has a very different sequence and is much shorter than the protein of SEQ ID NO:2.

The specification speculates, based on putative presence of a protein motif, that the protein encoded by the instant nucleic acid is an endonuclease III or a glycosylase (pg 42, lines 4-24), particularly a 5 -methylcytosine glycosylase (pg 44, lines 1-24). This conclusion is partly drawn because a mutation in an unrelated gene results in a reduction in genomic cytosine methylation and also results in phenotypic abnormalities in floral phenotype (pg 12-23). The specification also found weak homology between SEQ ID NO:2 and a series of protein fragments in the sequence databases and used those sequences to derive three consensus sequences, DMT Domains A, B and C (pg 42, line 24, to pg 43, line 28). However, the instant specification provides no evidence that SEQ ID NO:2 or any of these other proteins have the putative enzymatic function.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding proteins with 70% identity to SEQ ID NO:2. Making all possible single amino acid substitutions in an 1729 amino acid long protein like that encoded by SEQ ID NO:1 or 5 would require making and analyzing 19^{1729} nucleic acids; these proteins would have 99.9% identity to SEQ ID NO:2. Because nucleic acids encoding proteins with 70% identity to SEQ ID NO:2 would encode proteins with 518 amino acid substitutions, many more than 19^{1729} nucleic acids would need to be made and analyzed.

The specification teaches no assay to determine if any of the proteins encoded by nucleic acids encoding proteins comprising at least one of SEQ ID NOs:71-73 have this activity.

As the specification does not describe the transformation of any plant with any nucleic acid encoding a protein comprising at least one of SEQ ID NO:71-73, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with modulated flowering time, modulated chromosomal DNA methylation, modulated organ identity, modulated organ number, modulated meristem size or activity, modulated endosperm development, and/or modulated MEDEA gene expression, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

Applicant urges that the present claims are directed to nucleic acids encoding a protein comprising SEQ ID NOs:71, 72 or 73 and having at least one of 10 biological activities. Applicant urges that the experimentation necessary to identify a working embodiment of the instant invention is not undue and one of skill in the art could identify functional DMT sequences, as the size, structure and function of DMT nucleic acids are taught in the specification (response pg 12).

This is not found persuasive because the specification does not teach which structure is responsible for which function. The specification also does not teach exact hybridization or amplification conditions and probes/primers to use in isolation of the claimed nucleic acids. Additionally, the proteins within SEQ ID NOs:1-70 have a 10-fold variation in size.

Applicant urges that the specification teaches that DMT proteins can comprise a bipartitie nuclear localization signal, a leucine zipper sequence, a basic region, and/or an HhH-GPD motif.

Applicant urges that the function of DMT proteins is described throughout the specification as being involved in seed development and DNA methylation (response pg 12-13).

This is not found persuasive. The claims do not require that the DMT proteins comprise a bipartitie nuclear localization signal, a leucine zipper sequence, a basic region, and/or an HhH-GPD motif. The claims are not limited to a function of being involved in seed development and DNA methylation, but include 8 other possible functions.

Applicant urges that at most routine experimentation would be required to identify additional working embodiments within the scope of the claims using the BLAST algorithm. Applicant urges that SEQ ID NOs:1-70 represent sequences within the scope of the claims (response pg 13).

This is not found persuasive. None of the nucleic acids of SEQ ID NOs:1-70 encode a protein comprising SEQ ID NO:71, 72 or 73. Furthermore, many encode only incomplete protein fragments.

Applicant urges that variants can be made using the guidance on pg 20-36 of the specification. Applicant urges that even though the references cited in the prior Office action teach the unpredictability of making conservative substitutions, it is still a principle generally relied upon by skilled artisans, and thus provides enablement. Applicant also urges that basic molecular techniques taught in the application can be used to identify functional nucleic acids and plant transformation can be used to identify plants with any of the phenotypes associated with DMT (response pg 13-14).

This is not found persuasive because the specification provides no base sequence for which to make variant nucleic acids.

Applicant urges that because at least one SEQ ID NOs:71-73 are required, it would not be necessary to make and analyze 19^{1729} nucleic acids. Applicant also urges that one of skill in the art would know not to substitute the non-conserved residues within the consensus sequence or flanking the consensus sequences. Applicant also urges that the numerous examples of DMT sequences provided in the specification provide guidance for making amino acid substitutions (response pg 14).

This is not found persuasive. SEQ ID NOs:71-73 are 90, 230 and 292 amino acids long, respectively, and each comprise many possible variants ($2^{31} + 19^{16}$ for SEQ ID NO:71 alone). Thus, an undue number of variants would still need to be made and analyzed. Also, as the specification does not teach y DMT nucleic acids encoding proteins comprising SEQ ID NOs:71-73, no other DMT sequences can be used to provide guidance for making amino acid substitutions. Furthermore, Hill et al teaches that even using other sequences for making amino acids substitutions is unpredictable. Three histidines are maintained in ADP-glucose pyrophosphorylase across several species; one would expect that this position could tolerate either no or only conservative substations; however, it unexpectedly could tolerate nonconservative substitutions but not conservative ones (Hill et al, Table 1). Lastly, SEQ ID NO:2 is 1729 amino acids long, and SEQ ID NO:s71-73 together amount to only 407 amino acids; this leaves 1322 amino acids for which no guidance is provided as to which substitutions should be made.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1016:

> Conception of chemical compound requires that inventor be able to define compound so as to distinguish it from other materials, and to describe how to obtain it, rather than simply defining it solely by its principal biological property; thus, when inventor of gene, which is chemical compound albeit complex one, is unable to envision detailed constitution of gene so as to distinguish it from other materials, as well method for obtaining it, conception is not achieved until reduction to practice has occurred, and until after gene has been isolated.

> Conception of generalized approach for screening DNA library that might be used to identify and clone erythropoietin gene of then-unknown constitution is not conception of "purified and isolated DNA sequence" encoding human EPA, since it is not "definite and permanent idea of the complete and operative invention."

and at pg 1027

> ... despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-Type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

Applicant urges that the Office action did not indicate how any of the above-identified procedures are anything but routine. Applicant urges that cloning, sequencing, and Blast searching are among the most basic laboratory procedures. Applicant also urges that simple plant transformation methods can be then used to identify functional plant nucleic acids and that routine procedures have never been considered undue experimentation (response pg 14-).

This is not found persuasive. Given the vast number of possible variants of SEQ ID NO:2 and the lack of guidance for making those variants, and given that SEQ ID NO:2 itself does not comprising any of SEQ ID NOs: 71-73, means undue experimentation is required to make and use the claimed invention. The lack of guidance means making the claimed nucleic acids is not routine.

Applicant urges that sequence homology is not the only basis for the asserted enzymatic function of DMT as an endonuclease or glycosylase. Applicant urges that the structure of the full-length protein shows similarity in various domains and residues associated with the functionality of the enzymes, thus supporting the asserted function (response pg 15).

This is not found persuasive. As noted above, DMT (SEQ ID NO:2) does not comprise any of SEQ ID NOs:71-73 and thus cannot provide guidance for the structure/function

relationship of the claimed nucleic acids. Furthermore, neither homology not structural similarity provide evidence of function. Duggleby (1997, Gene 190:245-249) teach that "the function of any DNA sequence, whose identity is based solely on homology, can only be proven by experiments designed to evaluate that function" (pg 248, left column, paragraph 4).

Applicant urges that methods for assaying the asserted protein functions and methods for plant transformation are generally known to those skilled in the art and such persons would not need the disclosure to confirm the protein function. Applicant also urges that such guidance is provided on pg 37-39 and Examples 3 and 5 of the specification (response pg 15).

This is not found persuasive. The specification is required to teach the function and methods. pg 37-39 and Examples 3 and 5 of the specification only teach isolation of SEQ ID NO:1; it does not teach isolation of the claimed nucleic acids.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

15. Claims 1-2, 6-8, 13, 15-21, 24-26 and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 26 December 2002, as applied to claims 1-2, 4-

8, 13, 15-21 and 24-26, due to amendment of the claims. Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of DNA molecules that encode proteins comprising at least one of SEQ ID NOs:71-73 and that have any one of 10 biological activities. The specification does not describe any DNA molecules encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Hence, Applicant has not, in fact, described DNA molecules that encode proteins comprising at least one of SEQ ID NOs:71-73 and that have any one of 10 biological activities, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that the claims define the claimed genus of nucleic acids based on a structural feature of the proteins they encode (*i.e.*, comprising SEQ ID NO:71, 72 or 73). Applicant urges that the claims also define the claimed genus based on the functional features of the proteins they encode, *i.e.* having at least one of the recited 10 biological activities. Applicant urges that the structural and functional features have thus been described in detail (response pg 16-17).

This is not found persuasive. Recitation of 10 possible biological activities is not a specific recitation of function. Which structures correlate with which functions? Structure and specific function are not correlated in the claims as recited.

Applicant urges that the sequence listing provided 70 sequences that are encompassed by the pending claims. Applicant also urges that too much emphasis was placed on the number of representative sequences and not enough on the description of domains conserved among a large number of homologous sequences for many plant species; since the motifs are conserved across plant species, they represent sequences correlating to functions (response pg 17).

This is not found persuasive because none of the 35 protein sequences within SEQ ID NOs:1-70 comprise SEQ ID NOs:71, 72 or 73. Thus, the specification does not describe any of the very broad class of nucleic acids being claimed.

Applicant urges that the domains provide guidance to those of skill in the art to identify amino acid residues relevant to function and indicates possible alternatives to maintain function. Applicant urges that structural features distinguishing DMT polypeptides from others are provided and function is provided. Applicant urges that the structural features provide support for the genus and that testing every sequence comprising the domains is unreasonable and redundant (response pg 17-18).

This is not found persuasive because the specification must describe which amino acids are relevant to function. Further, as discussed above, the structures required for each function are not described. Testing every sequence within the genus is not required; however, the genus must be described within the full scope of the claims. The specification does not describe any nucleic acids within the scope of the claims.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997) at pg 1406:

> ... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

> ... the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

16. Claims 15-21 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 26 December 2002, as applied to claims 4-8, 13, 15-21 and 24-26, due to amendment. Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive.

Claim 18 is indefinite in its recitation of "modulating transcription." It is unclear which gene it is whose transcription is being modulated; thus the criteria for selecting a host cell with modulated transcription is unclear.

Applicant urges that DMT nucleic acids encode proteins capable of general modulation of gene transcription by epigenic means, which is not sequence specific and not limited to any particular gene or genes. Applicant urges that one of ordinary skill in the art would have no difficulty understanding the metes and bounds of the claims (response pg 19).

This is not found persuasive. The metes and bounds are not clear. For example, if transcription of some genes are decreased and transcription of others are increased such that overall, the level of transcription is the same of a non-transcribed plant, does this situation fall within the metes and bounds of the claims?

The following rejection is new, due to amendment:

Claim 15 lacks antecedent basis for the limitation "the polypeptide" in lines 2-3.

Double Patenting

17. Claims 1-3, 6-8, 13, 15-21, 24-26 and 30-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,476,296. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims drawn to nucleic acids encoding proteins with 80% identity to SEQ ID NO:2, expression cassettes, cells and plants transformed with those nucleic acids, and methods of using the expression cassettes to modulate transcription, as claimed in the issued patent, are a species of the genus of nucleic acids encoding proteins with 70% identity to SEQ ID NO:2 or comprising at least one of SEQ ID NOs:71-73, plants, cells and expression cassettes comprising those nucleic acids, and methods of using the expression cassettes to modify transcription, as claimed in the instant application. The rejection is repeated for the reasons of record as set forth in the Office action mailed 26 December 2002, as applied to claims 1-8, 13, 15-21 and 24-26. Applicant's arguments filed 30 June 2003 have been fully considered but they are not persuasive.

Applicant urges that they will consider providing a terminal disclaimer when the claims are indicated as otherwise allowable (response pg 21).

The rejection is held in abeyance.

18. Claims 8, 13, 17-21 and 24-26 are free of the prior art, given the failure of the prior art to teach or suggest constructs comprising the nucleic acid of claim 1 operably linked to a constitutive or heterologous promoter, plants and plant cells transformed with the nucleic acid of claim 1 and methods of using the nucleic acid to modulate transcription in plants or plant cells.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
September 10, 2003

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600